

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
Plaintiff,

v.

INHANCE TECHNOLOGIES LLC,
Defendant.

Civ. No. 5:22-CV-05055-JFM

**UNITED STATES' MEMORANDUM ADDRESSING THE ISSUES IDENTIFIED BY
THE COURT IN ITS ORDER DATED DECEMBER 4, 2023**

TABLE OF CONTENTS

I.	BACKGROUND	1
II.	ARGUMENT	4
	A. This Action Continues to Be Ripe	4
	1. Inhance Cannot Manufacture Long-Chain PFAS for a Significant New Use Unless and Until it Receives Authorization from EPA.....	5
	2. This Action Seeks to Enforce Inhance's Ongoing Failure to Comply with Sec. 5(a) of TSCA—Conduct that is Unlawful Regardless of the EPA Orders' Effectiveness	7
	B. This Action Is Not Moot	9
	C. Inhance's Motion to Dismiss is Ripe for Adjudication and Should be Denied	12
	D. The United States Will Seek to Withdraw Its Motion for Partial Summary Judgment as Superseded By Recent Developments	15
III.	CONCLUSION.....	15

TABLE OF AUTHORITIES

Cases

<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967).....	4, 6
<i>Bruni v. City of Pittsburgh</i> , 824 F.3d 353 (3d Cir. 2016)	14
<i>Califano v. Sanders</i> , 430 U.S. 99 (1977)	4
<i>Corliss v. O'Brien</i> , 200 F. App'x 80 (3d Cir. 2006).....	15
<i>Est. of Roman v. City of Newark</i> , 914 F.3d 789 (3d Cir. 2019).....	13
<i>Green v. Mansour</i> , 474 U.S. 65 (1985).....	1, 15
<i>In re Insilco Techs., Inc.</i> , 291 B.R. 628 (Bankr. D. Del. 2003)	3
<i>J.R. v. Camden City Bd. of Educ.</i> , No. 11-5060, 2013 WL 6074063 (D.N.J. Nov. 15, 2013) ...	2, 3
<i>Nat. Res. Def. Council, Inc. v. Texaco Refining & Mktg., Inc.</i> , 2 F.3d 493 (3d Cir. 1993)	10
<i>Peachlum v. City of York</i> , 333 F.3d 429 (3d Cir. 2003)	6
<i>Solar Turbines Inc. v. Seif</i> , 879 F.2d 1073 (3d Cir. 1989).....	10
<i>United States v. W.T. Grant Co.</i> , 345 U.S. 629 (1953).....	10
<i>Winkelman ex rel. Winkelman v. Parma City Sch. Dist.</i> , 550 U.S. 516 (2007).....	12

Statutes

5 U.S.C. § 706.....	8
15 U.S.C. § 2601 <i>et seq.</i>	1
15 U.S.C. § 2601(a)	8
15 U.S.C. § 2604(a)(1).....	passim
15 U.S.C. § 2604(a)(1)(A)	6
15 U.S.C. § 2604(a)(1)(A)(ii)	5, 11
15 U.S.C. § 2601(a)(1)(B)	5
15 U.S.C. § 2601(a)(1)(B)(i).....	12
15 U.S.C. § 2604(a)(1)(B)(i)-(ii)	5, 11
15 U.S.C. § 2604(a)(3)(A)	3
15 U.S.C. § 2601(a)(3)(B)(ii)(I)	3
15 U.S.C. § 2604(a)(3)(C)	11
15 U.S.C. § 2604(e)	3, 5

15 U.S.C. § 2604(e)(1)(A)	4, 5, 11
15 U.S.C. § 2604(e)(1)(A)(ii)(I)	3
15 U.S.C. § 2601(f).....	3, 5
15 U.S.C. § 2601(f)(1)	3
15 U.S.C. § 2604(f)(1)-(3).....	5
15 U.S.C. § 2601(f)(3)(A)	4, 8, 11
15 U.S.C. § 2614.....	2
15 U.S.C. § 2618(a)(1)(B)	8
15 U.S.C. § 2618(c)(1)(B)(i)(II)	8
28 U.S.C. § 2241.....	14

Rules

Fed. R. Civ. P. 8.....	3
Fed. R. Civ. P. 12(b)(6).....	13, 14
Fed. R. Civ. P. 12(d)	14
Fed. R. Civ. P. 56.....	14
Fed. R. Evid. 201	2

Regulations

40 C.F.R. § 721.10536	2, 8
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Other

<i>Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) (EPA 2023)</i>	4
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The United States of America (“United States”) submits this brief in response to the Court’s December 4, 2023 Order. Docket Item (“DI”) 70. As explained below, the United States continues to have a cause of action, and this case continues to be ripe. The Environmental Protection Agency (“EPA”) has completed its review of the Significant New Use Notices (“SNUNs”) submitted by Defendant Inhance Technologies LLC (“Inhance”) and issued administrative orders (“EPA Orders”) as a result of that review. The EPA Orders, which are not yet effective, prohibit Inhance from manufacturing nine species of long-chain PFAS subject to the Final Rule for the significant new use identified in the SNUNs. But regardless of the EPA Orders’ effectiveness, Inhance continues to fail to comply with Section 5(a)(1) of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2604(a)(1). Thus, the case remains ripe. For the same reason, the case is not moot: regardless of the EPA Orders’ effectiveness, Inhance remains out of compliance with Section 5(a)(1) and thus continues to violate federal law.

Because this case presents a live controversy, the Court should rule on—and deny—Inhance’s motion to dismiss, open discovery, and allow the parties to prepare for a trial on the merits of the United States’ claim for an injunction to halt Inhance’s ongoing violations of federal law. The United States plans to move to withdraw its motion for partial summary judgment because, due to the conclusion of EPA’s SNUN review, that motion now only concerns Inhance’s past violations of federal law. *See Green v. Mansour*, 474 U.S. 65, 73-74 (1985).

I. BACKGROUND

On December 19, 2022, the United States filed this action for declaratory and injunctive relief against Inhance for its past and continuing violations of the TSCA, 15 U.S.C. § 2601 *et seq.*, and its implementing regulations. DI 3 (“Compl.”). The complaint alleges that Inhance uses a process called “fluorination” to add barrier protection properties to plastic containers. As

a byproduct of this process, Inhance produces multiple per- and polyfluoroalkyl substances (“PFAS”—commonly known as “forever chemicals”—“subject to the Long-Chain PFAS Rule,” or Final Rule, 40 C.F.R. § 721.10536. Compl. ¶¶ 29, 30, 31 39, 51.

The complaint alleges that Inhance has and continues to fail to comply with Section 5(a)(1) of TSCA by manufacturing long-chain PFAS subject to the Final Rule for a significant new use before EPA has completed its review of Inhance’s SNUNs and without having received authorization from EPA to do so. Compl. ¶¶ 2, 4, 6, 7, 15, 24, 25, 46, 47, 55, 59, 65, 69. The complaint alleges that Inhance’s ongoing failure to comply with Section 5(a)(1) of TSCA is a violation of Section 15 of the statute. That provision makes it unlawful to “fail or refuse to comply with any requirement of . . . or any rule promulgated” under TSCA. 15 U.S.C. § 2614.

The United States’ complaint seeks a declaration that Inhance “has and continues to violate Section 15 . . . by failing or refusing to comply with . . . Section 5 . . . , and all applicable regulatory requirements.” Compl. at Relief Sought ¶ A. The United States also requests an injunction to, *inter alia*:

- (A) restrain the Defendant from any violation of Section 15 of TSCA . . . ;
- (B) restrain the Defendant from the manufacture or processing of PFAS for a significant new use subject to the [Final Rule], except in compliance with TSCA.

Id. Relief Requested ¶ B.

Thus, Inhance’s continuing violations of TSCA are the focus of the United States’ complaint. The United States asks this Court to take judicial notice of the completion of EPA’s SNUN review and issuance of the EPA Orders. But neither the EPA Orders’ issuance, nor their substance, alter the justiciability of the United States’ claims for violations of TSCA.¹ Out of an

¹ Under Federal Rule of Evidence 201, this Court can take judicial notice of the attached EPA Orders because they are adjudicative facts not subject to reasonable dispute. *See, e.g.*, *J.R.*

abundance of caution, the United States plans to move for leave to file an amended and/or supplemental complaint alleging that: (1) EPA has completed its review of Inhance’s SNUNs, (2) the agency has issued the EPA Orders, and (3) Inhance continues to manufacture long-chain PFAS, which is a failure to comply with Section 5(a)(1).²

Although the United States is not currently seeking to enforce the EPA Orders, the Government notes that the agency issued the orders under its Section 5(e) and 5(f) authority. 15 U.S.C. § 2604(e), (f); *see* Ex. 1 (redacted version of Section 5(e) Order), Ex. 2 (redacted version of Section 5(f) Order).³ Together, the EPA Orders prohibit Inhance from manufacturing the nine species of PFAS subject to the Final Rule for the significant new use identified in the SNUNs.

The Section 5(f) Order is based on EPA’s determination, pursuant to Sections 5(a)(3)(A) and 5(f)(1) of TSCA, 15 U.S.C. § 2604(a)(3)(A), (f)(1), that Inhance’s manufacture of three of the chemical substances (PFOA, PFNA and PFDA) for a significant new use presents an unreasonable risk of injury to health or the environment. Ex. 2 at 3. The Section 5(e) Order is based on EPA’s determination, pursuant to Section 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, 15 U.S.C. § 2604(a)(3)(B)(ii)(I), (e)(1)(A)(ii)(I), that in the absence of sufficient information, Inhance’s

v. Camden City Bd. of Educ., No. 11-5060, 2013 WL 6074063, at *1 n.1 (D.N.J. Nov. 15, 2013); *In re Insilco Techs., Inc.*, 291 B.R. 628, 633 n.7 (Bankr. D. Del. 2003).

² Under Federal Rule of Civil Procedure 8’s notice-pleading standard, taking the facts alleged in the United States’ present complaint, TSCA’s statutory scheme, and judicial notice of the issuance of the EPA Orders, the United States’ complaint remains live before any amendment or supplementation.

³ The Court granted the United States’ motion for leave to file under seal the unredacted version of the EPA Orders. DI 72.

manufacture of the other six chemical substances (PFDoA, PFuDA, PFTeDA, PFTrDA, PFHxDA, and PFoDA) for a significant new use “may present an unreasonable risk” of injury.⁴ Ex. 1 at 3.

The SNUN review period expires on February 28, 2024. Under Section 5(e)(1)(A) and 5(f)(3)(A), the EPA Orders do not become effective until the SNUN review period expires. 15 U.S.C § 2604(e)(1)(A), (f)(3)(A).

II. ARGUMENT

A. This Action Continues to Be Ripe

As the United States has argued, DI 25 (U.S.’ Opp. to Motion to Dismiss); DI 52 (U.S.’ Reply in Support of Motion for Partial Summary Judgment),⁵ Defendant’s subject-matter jurisdiction argument should be rejected because this enforcement action is ripe for judicial review. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). The United States’ complaint was ripe before the EPA Orders were issued because Section 5(a)(1) of TSCA clearly prohibits any person from manufacturing any chemical substance for a significant new use *unless and until* EPA grants authorization to manufacture—and EPA had not granted Inhance such authorization.

And following the issuance of the EPA Orders, the complaint continues to be ripe for the same reason: Section 5(a)(1) continues to prohibit Inhance from manufacturing long-chain PFAS subject to the Final Rule for a significant new use because EPA has not authorized Inhance to engage in such manufacture.

⁴ EPA determined that all nine PFAS are persistent, bioaccumulative, and toxic (“PBT”). Consistent with the EPA’s 2023 *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)*, the Section 5(e) Order requires a full suite of testing to be completed and submitted to EPA for review prior to considering authorizing the manufacture of PBT PFAS in situations where consumer exposure to the PBT PFAS is expected.

⁵ The United States incorporates by reference these filings and the arguments therein.

The fact that the EPA Orders are not yet effective is relevant to the United States' ability to enforce those orders. But it is clear from Section 5(a)(1)'s text and purpose that, regardless of the EPA Orders' effectiveness, Inhance remains out of compliance with TSCA's mandate.

1. Inhance Cannot Manufacture Long-Chain PFAS for a Significant New Use Unless and Until it Receives Authorization from EPA

To protect public health and the environment from unreasonable risks posed by chemical substances, Congress codified a precautionary approach in Section 5(a)(1) of TSCA. Section 5(a)(1)(A)(ii) of TSCA sets forth a broad proscription: "no person may . . . manufacture . . . any chemical substance for a . . . significant new use." 15 U.S.C. § 2604(a)(1)(A)(ii). This prohibition, however, is modified by Section 5(a)(1)(B). Under this provision, a "person"—here, Inhance—"may" engage in such manufacture only "if" (1) it submits a SNUN to EPA before initiating such manufacture and (2) after the agency completes its review of the SNUN, the person "complies with any applicable requirement of, or imposed pursuant to," *inter alia*, orders issued by EPA under Sections 5(e) and 5(f) of TSCA. 15 U.S.C. § 2604(a)(1)(B)(i)-(ii).⁶ Unless and until all of the steps and requirements of Section 5(a)(1)(B) are complete and complied with, Section 5(a)(1)(A)(ii)'s prohibition on manufacturing for a significant new use applies.

⁶ Under Section 5(e)(1)(A), if EPA determines that it lacks sufficient information to make a "reasoned evaluation of the health and environmental effects of a chemical substance," then the agency "shall issue an order . . . to prohibit or limit the manufacture . . . of such substance . . . to the extent necessary to protect against an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(e)(1)(A). Similarly, under Section 5(f)(1)-(3), if EPA determines that a chemical substance or significant new use "presents an unreasonable risk of injury to health or environment," then EPA "shall" either issue (a) a proposed rule that applies to the chemical substance or (b) "an order to prohibit or limit the manufacture" of the chemical substance. 15 U.S.C. § 2604(f)(1)-(3). Thus, whenever EPA makes a risk determination under Sections 5(e) or 5(f) relating to manufacturing, EPA must, to the extent necessary, issue a rule or proposed order regulating such activity.

Thus, under Section 5(a)(1)'s scheme, Inhance may manufacture long-chain PFAS for a significant new use only if EPA affirmatively authorizes such manufacture, and Inhance complies with the terms of any orders imposed by EPA. Because EPA has not authorized Inhance to manufacture any long-chain PFAS for a significant new use, Section 5(a)(1)(A) continues to prohibit Inhance from engaging in such manufacture. And because Inhance has failed to comply with this provision (1) before it submitted SNUNs, (2) during the SNUN review, and (3) since EPA completed its review, Inhance has and continues to violate TSCA. Thus, this case continues to be ripe.

Even under the erroneous ripeness theory that Inhance advanced in its earlier filings, this case is undoubtedly ripe. DI 10 (Motion to Dismiss); DI 27 (Opp. to Motion for Partial Summary Judgment). Inhance has repeatedly asserted that the United States' complaint was not ripe because EPA had not completed its review of the SNUNs and made determinations on them. *E.g.*, DI 10-1 at 5-8; DI 27 at 1. Inhance has thus strongly implied that this case *would be* ripe once the agency completed its review and if—as occurred here—EPA did not authorize Inhance's manufacture of long-chain PFAS for a significant new use. Now that EPA's review is complete and it has issued orders, Inhance's premise for why this case is unripe no longer applies.

This case continues to meet the two-part test for ripeness because: (1) the issues are fit for judicial review and (2) the public will suffer hardship if the court withholds consideration. DI 25 at 9-11. *See Abbott Labs*, 387 U.S. at 149. In determining ripeness, “[t]he question in each case is whether the facts alleged show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to justify judicial resolution.”

Peachlum v. City of York, 333 F.3d 429, 434 (3d Cir. 2003) (quotation marks omitted).

Given Inhance’s continued manufacture of long-chain PFAS—both before and after the agency issued the EPA Orders—the parties have adverse interests. *Id.* at 433-34. In addition, the complaint alleges ongoing violations of Section 5(a)(1) of TSCA that are ripe for judicial resolution. *Id.* at 433. Here, the United States alleges that Inhance currently manufactures for a significant new use PFAS subject to the Final Rule that may present an unreasonable risk of injury to public health and the environment. Compl. ¶¶ 31, 39, 45, 47, 49. Because the complaint alleges ongoing violations of federal law that are judicially redressable, the public will suffer hardship if the Court withholds consideration.

Based on its analysis of the ripeness cases it cited, Inhance argued “neither party to this litigation will suffer hardship from deferring judicial intervention until after EPA has completed its review of the SNUNs Inhance submitted to the agency.” DI 10-1 at 8. The United States disagreed. DI 25 at 9-11. Even if Inhance were correct (and it is not), its argument no longer applies. The same is true of Inhance’s argument that the complaint is not ripe because a judgment would lack utility “before EPA has completed” SNUN review DI 10-1 at 9.

In short, this case was ripe when it was filed, and it remains ripe now that the EPA has completed its review of Inhance’s SNUNs.

2. This Action Seeks to Enforce Inhance’s Ongoing Failure to Comply with Sec. 5(a)(1) of TSCA—Conduct that is Unlawful Regardless of the EPA Orders’ Effectiveness

On December 7, 2023, Inhance filed a petition for review in the Fifth Circuit challenging the EPA Orders. Ex. 3. Inhance has moved in the appeals court for expedited briefing and a stay of the orders pending appeal. Ex. 4 at 8. The United States does not oppose Inhance’s proposed expedited briefing schedule or the entry of an administrative stay pending issuance of the mandate. *Id.* at 7.

The appellate action does not render the United States' enforcement action in this Court unripe—either constitutionally or prudentially—for judicial review. The appellate case concerns the validity of the not-yet-effective EPA Orders. This action, by contrast, seeks to remedy Inhance's ongoing failure to comply with Section 5(a) of TSCA. Critically, Inhance's ongoing failure to comply with Section 5(a) is unlawful *regardless of the EPA Orders' effectiveness*.

The Fifth Circuit has jurisdiction to review the EPA Orders under Section 19 of TSCA, U.S.C. § 2618(a)(1)(A).⁷ It also has jurisdiction to grant appropriate relief under the Administrative Procedure Act (“APA”), 5 U.S.C. 706, and, under TSCA Section 19(c)(1)(B), to “hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record.” 15 U.S.C. § 2618(c)(1)(B)(i)(II). Under these provisions, the Fifth Circuit's review will be limited to the administrative record, and it will apply the APA's standards of review.

The EPA Orders address and satisfy EPA's obligations to review and make determinations regarding the risks posed by the significant new uses of the chemical substances that are the subject of Inhance's SNUNs. In its recent notice, Inhance contended that the EPA Orders do not address legal issues raised in this case, including:

- (i) whether the Significant New Use Rule (SNUR) at issue in this lawsuit, 40 C.F.R. § 721.10536, applies to Inhance or its fluorination process; (ii) whether the fluorination process constitutes a ‘new use’; (iii) whether the PFAS inadvertently generated during fluorination constitutes an impurity or a byproduct; and (iv) whether Inhance had fair notice of EPA's position on all of these issues.

DI 69 at 1.

⁷ That jurisdiction, however, is not exclusive. 15 U.S.C. § 2618(a)(1)(B) (providing that jurisdiction in the court of appeals is exclusive “other than in an enforcement proceeding”).

These questions are presented—and ripe for resolution—in this enforcement action.⁸

Inhance’s recently filed petition for review does not change this conclusion. The United States intends to take the position that those questions are not properly before the Fifth Circuit but should instead be resolved in this enforcement action. And regardless of the positions taken by the parties,⁹ the Fifth Circuit could decide that such issues are not properly before it. In any event, the violations alleged here do not turn on the validity of the EPA Orders but instead are predicated on Inhance’s ongoing failure to comply with Section 5(a)(1) of TSCA.

This case is ripe, and the Court should allow it to proceed.

B. This Action Is Not Moot

The United States’ cause of action and complaint are not moot because Inhance continues to violate Section 5(a)(1) of TSCA by manufacturing long-chain PFAS subject to the Final Rule for a significant new use without authorization to do so. As with ripeness, the fact that the EPA Orders have been issued but are not yet effective does not bear on the question of mootness. Under Section 5(a)(1) of TSCA, Inhance’s manufacture of long-chain PFAS was unlawful before the company submitted its SNUNs; it was unlawful after the company submitted its SNUNs and during the review period; and it continues to be unlawful.

Here, Defendant’s allegedly unlawful conduct is ongoing. Inhance has not even alleged that it has voluntarily ceased its challenged conduct, i.e., its manufacture of long-chain PFAS

⁸ As explained below, issues (i)-(ii), and (iv) are inappropriate for resolution at the motion-to-dismiss stage, *see infra* section II.C, and issue (iii) is only presented in the United States’ now-moot motion for summary judgment, not Inhance’s motion to dismiss. *See infra* section II.D.

⁹ In its motion for a stay in the Fifth Circuit, rather than challenging the EPA Orders directly, Inhance rehashes the arguments it asserted in this case regarding whether it is subject to the Final Rule or received fair notice. Ex. 4 at 14.

subject to the Final Rule for a significant new use.¹⁰ Instead, in its recent notice, Inhance has argued—without evidentiary support—that the EPA Orders “will shut down [its] fluorination process entirely,” suggesting that it cannot fluorinate without manufacturing long-chain PFAS and that it is continuing to fluorinate and thereby manufacture such PFAS. DI 69 at 2.

As with its ripeness argument, the fact that the EPA has issued orders on Inhance’s SNUNs forecloses Inhance’s mootness argument. Inhance previously asserted that the United States’ complaint might become moot if the EPA determined that Inhance’s manufacture of long-chain PFAS does not present an unreasonable risk of injury to public health and the environment. DI 10-1 at 1, 5, 7-8; DI 49 at 11 (Opp. to U.S. Motion for Partial Summary Judgment). That did not happen. Once again, under Inhance’s own line of argument, this case is justiciable.

The pendency of Inhance’s petition for review in the Fifth Circuit does not render the United States’ enforcement action in this Court moot. Inhance—which earlier claimed this case was unripe—now suggests the case is moot because the EPA Orders are not yet effective. DI 74 at 1-2. But if Inhance were right (it is not), that would mean there is no cause of action under Section 5(a)(1) unless EPA issues orders that have taken effect, and an entity violates those orders. That would gut the 2016 Amendments to Section 5(a)(1). DI 52 at 2-3. Although EPA has issued prohibitory orders, only this Court can enjoin Defendant for its continued failure to comply with Section 5(a)(1).

¹⁰ Inhance’s continuing conduct in violation of TSCA plainly undermines any suggestion of mootness. This situation is even more egregious than the “voluntary cessation” cases, which establish that even the halting of allegedly unlawful conduct “does not deprive the tribunal of power to hear and determine the case, i.e., does not make the case moot.” *United States v. W.T. Grant Co.*, 345 U.S. 629, 632 (1953). *Id.*; *see Nat. Res. Def. Council, Inc. v. Texaco Refining and Mktg., Inc.*, 2 F.3d 493 (3d Cir. 1993); *Solar Turbines Inc. v. Seif*, 879 F.2d 1073 (3d Cir. 1989).

Similarly, the Court should reject any argument that Inhance may lawfully manufacture under Section 5(a)(1) merely because EPA’s SNUN review is complete, and the EPA Orders are not currently effective—whether because the SNUN review period has not expired or because the orders may be stayed administratively pending appeal. Such an argument would presumably rest on the language in Section 5(a)(1)(B)(i)-(ii). That provision states that an entity may manufacture for a significant new use if (1) it submits a SNUN “at least 90 days before” commencing such manufacturing, (2) EPA completes its SNUN review, and (3) the entity “complies with any applicable requirement . . . imposed” by an EPA order relating to the SNUNs. Because the EPA Orders are not currently effective, the argument may go, there are no applicable requirements imposed by them. But unless and until Inhance complies with all the requirements of Section 5(a)(1)(B)(i)-(ii), Inhance is prohibited from manufacturing long-chain PFAS for a significant new use. 15 U.S.C § 2604(a)(1)(A)(ii).¹¹

Consider the implications of a contrary conclusion: because any EPA orders do not become effective until the SNUN review period expires, 15 U.S.C § 2604(e)(1)(A), (f)(3)(A), an entity would be authorized to manufacture for a significant new use at the end of EPA’s review of the SNUNs so long as the review period had not yet expired. So, even if EPA issues orders that prohibit manufacture, an entity could manufacture in the period between the issuance of those orders and their effective date. This would be an incongruous result. *See Winkelman ex rel. Winkelman v. Parma City Sch. Dist.*, 550 U.S. 516, 531 (2007) (rejecting reading of statute

¹¹ There is only one circumstance where Section 5 does not contemplate that prohibitions or restrictions will be imposed following completion of the SNUN review. That situation arises where EPA determines that the significant new use “is not likely to present an unreasonable risk of injury to health or the environment.” Section 5(a)(3)(C), 15 U.S.C. § 2604(a)(3)(C). In that case, “the submitter of the notice may commence manufacture.” *Id.* Of course, that is not the situation here.

that would produce “incongruous results”). Likewise with allowing manufacture if the EPA Orders are stayed.¹² The precautionary principle that Section 5(a)(1) embodies would be directly contravened if the case were deemed moot merely because the EPA Orders are not currently effective.

C. Inhance’s Motion to Dismiss is Ripe for Adjudication and Should be Denied

This action is live, and the Court should decide and deny Inhance’s pending motion to dismiss. DI 10. The recent administrative developments only underscore that the legal arguments raised by Inhance—regarding justiciability, EPA’s SNUR authority to regulate Inhance’s manufacture of long-chain PFAS, and fair notice—are fit for review. The Court should reject Inhance’s arguments.

Because EPA has completed its administrative review of Inhance’s SNUNs and taken final action relating to them, Inhance’s justiciability argument itself is moot. And as the United States explained in its opposition to Inhance’s motion to dismiss, Inhance’s challenge to the Final Rule and fair notice arguments are premised on facts outside of the pleadings; thus, they cannot be properly resolved at the motion-to-dismiss stage. DI 25 at 16-17, *especially* n.12. Even if the Court were to venture outside the pleadings and convert Inhance’s motion into one for summary judgment, Inhance itself has asserted that the legal issues it wishes to resolve as a matter of law in its motion to dismiss turn on disputed questions of fact. DI 49 at 7-8. Moreover, as the United States has explained, Inhance’s legal arguments regarding the SNUR and fair notice fail as a matter of law. DI 25 at 15, 27; DI 37 at 18-22.

¹² Indeed, under such an overly formalistic, mechanical reading of the statute, Inhance would *never* be allowed to lawfully manufacture long-chain PFAS for a significant new use because, as it has conceded, it did not “submit[]” SNUNs “at least 90 days before such manufacture.” 15 U.S.C. § 2604(a)(1)(B)(i). That, too, would be an absurd result.

For any number of reasons, then, Inhance’s motion to dismiss (or for summary judgment) must be denied, and the case should proceed to discovery.¹³ Inhance’s first argument in its motion to dismiss is that “[t]his Court should . . . dismiss or defer its review of Plaintiff’s claims until the [EPA] completes its review of the significant new use notices.” DI 10-1 at 5. That justiciability argument no longer applies and is moot.

Inhance next argued in its motion that EPA lacks the statutory authority to regulate its production of long-chain PFAS through a SNUR because SNURs cannot apply to a “preexisting” use of a chemical substance. DI 10 at 1. As the United States explained in its opposition brief, Inhance’s argument rests on the naked factual assertion that Inhance has such a preexisting use of long-chain PFAS. DI 25 at 10-12. And:

[i]n ruling on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), courts consider only the “‘complaint, exhibits attached to the complaint, and matters of public record’” and “documents ‘that a defendant attaches as an exhibit to a motion to dismiss,’ if they are ‘undisputedly authentic’ and ‘the plaintiff’s claims are based on them.’” *Est. of Roman v. City of Newark*, 914 F.3d 789, 796 (3d Cir. 2019). . . . Here, no such sources have been presented . . . indicating that Inhance manufactured PFAS subject to the Final Rule before the Rule was proposed. [Nor are the United States’ claims based on such an assertion.] Thus, Inhance’s motion hinges on unsupported factual assertions that the Court should ignore for purposes of ruling on the present motion.

DI 25 at 17 n.12. Thus, Inhance’s argument about EPA’s SNUR authority cannot be resolved on a motion to dismiss.

Under Rule 12(d), “[i]f, on a motion under Rule 12(b)(6) . . . , matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.” Fed. R. Civ. P. 12(d); *see also Bruni v. City of Pitt.*, 824 F.3d 353, 360-61 (3d Cir. 2016). Again, no material beyond the pleadings was presented in

¹³ The United States incorporates by reference its opposition to Inhance’s motion to dismiss, DI 25, and its reply in support of its motion for partial summary judgment. DI 52.

Inhance's motion. The plain language of the Rules, and prudence, counsel for treating Inhance's motion as what it purports to be—a motion under Rule 12(b)(6)—rather than converting it into one for summary judgment. And the Rule 12(b)(6) motion should be denied for the reasons already stated.

If the Court elects to treat *Inhance*'s filing as a Rule 56 motion by considering the submissions related to the *United States*' motion for summary judgment, then Inhance's motion still fails. Initially, the United States notes that it has not located any cases where courts converted a motion to dismiss into one for summary judgment in this posture. Also, as mentioned, the United States incorporates the arguments in its opposition to Inhance's motion to dismiss concerning Defendant's affirmative defenses, i.e., preexisting use and fair notice. DI 25 at 14-27. These arguments apply with equal force if Inhance's motion is treated as one for summary judgment.

Last, the United States observes that in its opposition to the Government's motion for summary judgment, Inhance argued that disputed fact issues exist regarding its preexisting-use, impurity, and fair-notice defenses. DI 49 at 10, 14-17. Thus, under Inhance's own theory, it is not entitled to summary judgment. Moreover, as the United States has explained, Inhance received fair notice as a matter of law, and no discovery is warranted on this question. DI 52 at 10-11, 18-22. Under either argument, Inhance is not entitled to summary judgment.

The Court should deny Inhance's motion to dismiss and authorize discovery.

D. The United States Will Seek to Withdraw Its Motion for Partial Summary Judgment as Superseded By Recent Developments

The United States acknowledges that its motion for partial summary judgment, DI 37, is now moot, and will move to withdraw that motion. The summary judgment motion sought a declaration under the Declaratory Judgment Act, 28 U.S.C. § 2241. The motion requested a

ruling that Inhance was liable under TSCA for its manufacture for significant new uses of “PFAS subject to the Final Rule before EPA ha[d] completed its review of the notices and determined whether to authorize Inhance’s manufacturing and, if so, whether any restrictions on the manufacturing must be imposed.” DI 37 at 4.

As the Court is aware, following the filing of the United States’ motion, EPA completed its review of Inhance’s SNUNs, made risk determinations, and issued orders based on its determinations. *See* Exs. 1 and 2. Due to this intervening development, the Government’s motion for partial summary judgment—which exclusively concerns Inhance’s conduct before EPA completed its review of the SNUNs—addresses only Inhance’s past violations of federal law. Thus, the United States will move to withdraw that motion. *See Green*, 474 U.S. at 73-74; *Corliss v. O’Brien*, 200 F. App’x 80, 84 (3d Cir. 2006).

III. CONCLUSION

For the foregoing reasons, the United States’ action is ripe and not moot. The Court should deny Inhance’s motion to dismiss, and this case should proceed to discovery. The United States will move to withdraw its motion for partial summary judgment.

Dated: December 11, 2023

Respectfully submitted,

FOR THE UNITED STATES OF AMERICA

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CERTIFICATE OF SERVICE

The foregoing Memorandum Addressing the Issues Identified By The Court In Its Order Dated December 4, 2023 has been filed electronically using the ECF system and is available for viewing and downloading from the ECF system. Counsel for the Plaintiff also has served by email an electronic copy of this Memorandum on counsel for Defendant and counsel for the Intervenor-Plaintiffs.

DATE: December 11, 2023

/s/ Richard Gladstein
RICHARD GLADSTEIN